

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

ISIS PHARMACEUTICALS, INC., a  
Delaware Corporation, ) Case No. 3:11-cv-2214-GPC-KSC  
v. Plaintiff, )  
SANTARIS PHARMA A/S CORP., a )  
Delaware Corporation, and )  
SANTARIS PHARMA A/S, a Danish )  
Corporation, )  
Defendants. )  
AND RELATED COUNTERCLAIMS. )  
ORDER DENYING  
DEFENDANTS' MOTION FOR  
RECONSIDERATION  
(ECF NO. 258)

Prior to this patent infringement case's transfer to the undersigned, the Honorable Barry Ted Moskowitz, Chief Judge, denied Defendants' first motion for summary judgment as to whether Defendants' allegedly infringing conduct fell within the "safe harbor" provided by 35 U.S.C. § 271(e)(1). (ECF No. 53.) On February 27, 2014, after a lengthy period of limited discovery, this Court denied Defendants' second motion for summary judgment on the safe harbor issue. (ECF No. 250.)

Presently before the Court is Defendants' motion for reconsideration of this Court's February 27, 2014 order, (ECF No. 258), which has been fully briefed, (ECF

1 Nos. 266, 268), and which the Court finds suitable for disposition without oral  
 2 argument, see CivLR 7.1.d.1.

3 Defendants ask the Court to reconsider three aspects of its February 27, 2014  
 4 order:

- 5 1. The Court's reading of Classen Immunotherapies, Inc. v. Biogen IDEC,  
   6 659 F.3d 1057 (Fed. Cir. 2012), and Momenta Pharmaceuticals, Inc. v.  
   7 Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), as  
   8 standing for the proposition that, "regardless of the stage of the regulatory  
   9 process in which a patented invention is used to obtain information, the  
   10 information derived from using the patented invention must be  
   11 'reasonably related' to the type of information required by the FDA at  
   12 some point during the regulatory process."
- 13 2. The Court's conclusion that Santaris's act of entering into contracts with  
   14 U.S. pharmaceutical companies to discover and develop drugs that the  
   15 pharmaceutical companies may submit to the FDA does not, as a matter  
   16 of law, fall within the safe harbor.
- 17 3. The Court's conclusion that the term "patented invention," as used in 35  
   18 U.S.C. § 271(e)(1), means inventions that would be eligible for a patent  
   19 extension under 35 U.S.C. § 156 or inventions that are themselves subject  
   20 to regulatory approval.

21 (ECF No. 258-1.)

22 In the alternative, Defendants ask the Court to certify its February 27, 2014 order  
 23 for interlocutory appeal.

24 **1. Reconsideration**

25 **a. Legal Standards**

26 District courts have the discretion to reconsider interlocutory rulings until a final  
 27 judgment is entered. Fed. R. Civ. P. 54(b); United States v. Martin, 226 F.3d 1042,  
 28 1048-49 (9th Cir. 2000). While the Federal Rules of Civil Procedure do not set forth

1 a standard for reconsidering interlocutory rulings, the “law of the case” doctrine and  
 2 public policy dictate that the efficient operation of the judicial system requires the  
 3 avoidance of re-arguing questions that have already been decided. See Pyramid Lake  
 4 Paiute Tribe of Indians v. Hodel, 882 F.2d 364, 369 n.5 (9th Cir. 1989).

5 As such, most courts adhere to a fairly narrow standard by which to reconsider  
 6 their interlocutory rulings. This standard requires that the party show: (1) an  
 7 intervening change in the law; (2) additional evidence that was not previously  
 8 available; or (3) that the prior decision was based on clear error or would work  
 9 manifest injustice. Id.; Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.,  
 10 571 F.3d 873, 880 (9th Cir. 2009); Sch. Dist. No. 1J v. ACandS, Inc., 5 F.3d 1255, 1263  
 11 (9th Cir. 1993).

12 Reconsideration is an “extraordinary remedy, to be used sparingly in the interests  
 13 of finality and conservation of judicial resources.” Kona Enters., Inc. v. Estate of  
 14 Bishop, 229 F.3d 877, 890 (9th Cir. 2000). ““A motion for reconsideration is not an  
 15 opportunity to renew arguments considered and rejected by the court, nor is it an  
 16 opportunity for a party to re-argue a motion because it is dissatisfied with the original  
 17 outcome.”” FTC v. Neovi, Inc., 2009 WL 56130, at \*2 (S.D. Cal. Jan. 7, 2009)  
 18 (quoting Devinsky v. Kingsford, 2008 WL 2704338, at \*2 (S.D.N.Y. July 10, 2008)).

19 In addition to these substantive standards, Civil Local Rule 7.1.i.1 requires a  
 20 party moving for reconsideration to submit an affidavit or certified statement of an  
 21 attorney

22 setting forth the material facts and circumstances surrounding each prior  
 23 application, including *inter alia*: (1) when and to what judge the  
 24 application was made, (2) what ruling or decision or order was made  
 25 thereon, and (3) what new or different facts and circumstances are claimed  
 26 to exist which did not exist, or were not shown, upon such prior  
 27 application.

28 Rule 7.1.i.2 provides that “any motion or application for reconsideration must be filed  
 29 within twenty-eight (28) days after the entry of the ruling, order or judgment sought to  
 30 be reconsidered.”

## b. Analysis

2 Before proceeding to the merits of Defendants' motion for reconsideration, the  
3 Court addresses Plaintiff's argument that the attorney declaration Defendants filed in  
4 support of their motion for reconsideration fails to comply with Rule 7.1.i.1 because  
5 it fails to identify new or different facts and circumstances that did not exist before.  
6 The Court also addresses Plaintiff's argument that Defendants' motion for  
7 reconsideration is untimely under Rule 7.1.i.2 because, more than two years ago,  
8 "Judge Moskowitz reached essentially the same conclusions of law about which  
9 Santaris now complains." More specifically, Plaintiff asserts "Santaris's contentions  
10 that the uncertain nature of its contracts does not vitiate the Safe Harbor protection and  
11 that the Safe Harbor extends to situations in which a biological compound is used as  
12 a 'research tool' were squarely rejected by Judge Moskowitz."

13        Here, the Court agrees that Defendants have failed to submit an affidavit or  
14 certified attorney statement that complies with Rule 7.1.i.1 because the declaration  
15 provided by Defendants does not set forth any new or different facts and circumstances  
16 that did not exist before. (See ECF No. 258-2 at 4-5.) Instead, the declaration merely  
17 summarizes the arguments Defendants make in their motion for reconsideration. (Id.)  
18 This is a sufficient basis on which to deny Defendants' motion for reconsideration. See  
19 FTC v. Neovi, Inc., 2009 WL 56130, at \*2 (S.D. Cal. Jan. 7, 2009) (Sammartino, J.).

20 The Court further agrees that Defendants' second and third claims of error are  
21 untimely, as they were considered and rejected by Judge Moskowitz in an order issued  
22 more than one and a half years before Defendants filed the instant motion for  
23 reconsideration. The Court further finds Defendants' second and third claims of error  
24 are reiterations of arguments previously made and rejected. The Court will thus  
25 explain its reasoning as to the second and third claims of error, after which the Court  
26 will address the substance of Defendants' first claim of error.

27 In their second claim of error, Defendants argue this Court erred in concluding  
28 that Santaris's act of entering into collaboration agreements with U.S. pharmaceutical

1 companies does not fall within the safe harbor as a matter of law but instead requires  
 2 a factual determination as to whether said act is “reasonably related” to the type of  
 3 information submitted to the FDA for regulatory approval.

4 Defendants have now had three opportunities (including Defendants’ first  
 5 motion for summary judgment, second motion for summary judgment, and the instant  
 6 motion for reconsideration) to argue that the act of entering into the collaboration  
 7 agreements fell within the safe harbor. In support of their second motion for summary  
 8 judgment, Defendants argued:

9 It is of no moment that Santaris A/S did not yet know the structure of a  
 10 particular Target or ASO compound [at the time it entered into the  
 11 collaboration agreements with U.S. pharmaceutical companies], because  
 12 Information obtained on the binding and other in vitro properties of each  
 13 Library compound may be relevant to FDA submissions on that  
 14 compound as an investigational drug.

15 (ECF No. 213 at 21.) In denying Defendants’ second motion for summary judgment,  
 16 the Court considered these uncertainties, finding:

17 the collaboration agreements generally required Santaris to (1) wait for its  
 18 U.S. collaborators to select a target, (2) develop a library of antisense  
 19 compounds for each selected target, and (3) screen each compound in the  
 20 library for its effect on a given target using, among other tools, Isis’s  
 21 patented inventions. Then, after even more work by the U.S.  
 22 pharmaceutical companies, information from Santaris’s research results  
 23 might be submitted to the FDA in connection with an IND.

24 (ECF No. 250 at 19.) Then, after noting the dissimilarities between the facts of this  
 25 case and those of Merck KGaA v. Integra Lifesciences I, Ltd, 545 U.S. 193 (2005), the  
 26 Court concluded summary judgment was not appropriate. Instead, the Court concluded  
 27 that

28 what is left to determine is whether Santaris’s collaboration agreements  
 29 are “reasonably related” to the type of information submitted to the  
 30 FDA—that is, whether it was “objectively reasonable for a party in  
 31 [Santaris’s] . . . situation to believe that there was a decent prospect that  
 32 the accused activities would contribute, relatively directly, to the  
 33 generation of the kinds of information that are likely to be relevant in the  
 34 processes by which the FDA would decide whether to approve the  
 35 product in question.”

36 (ECF No. 250 at 20.)

1        In denying Santaris's first motion for summary judgment, Judge Moskowitz  
 2 "decline[d] to resolve Santaris's claim to the Safe Harbor exemption without a more  
 3 specific analysis of Santaris's uses of the allegedly infringing compounds, methods,  
 4 and processes." (ECF No. 53 at 8.) Judge Moskowitz then stated:

5        To the extent Santaris is selling and/or licensing infringing "platform"  
 6 technology so that another company can "discover and develop" drug  
 7 candidates—rather than developing and/or licensing/selling specific drug  
 candidates itself—Santaris could be using or selling patented technology  
 to perform "basic scientific research."

8 [Id. at 9 (citing Merck, 545 U.S. at 207.)

9        It is thus clear that both this Court and Judge Moskowitz have considered the  
 10 uncertainties that existed in the collaboration agreements at the time of contracting.  
 11 And, based on these uncertainties, both this Court and Judge Moskowitz found  
 12 summary judgment inappropriate. In other words, two courts have now concluded that  
 13 Santaris's entering into the collaboration agreements is not, as a matter of law,  
 14 protected by the safe harbor. Thus, in addition to concluding that Defendant's second  
 15 claim of error is untimely under Civil Local Rule 7.1.i.2, the Court finds Defendants  
 16 have merely reiterated an argument that two courts have considered and rejected. The  
 17 Court will therefore deny Defendants' motion for reconsideration as to the second  
 18 claim of error.

19        Defendants' third claim of error suffers the same fate. Defendants argue the  
 20 Court erred in concluding the term "patented invention," as used in 35 U.S.C. §  
 21 271(e)(1), means inventions that would be eligible for a patent extension under 35  
 22 U.S.C. § 156 or inventions that are themselves subject to regulatory approval. Again,  
 23 however, two courts have considered and rejected Defendants' position on the meaning  
 24 of "patented invention" as used in 35 U.S.C. § 271(e)(1).

25        In support of its second motion for summary judgment, Santaris argued  
 26 Plaintiff's patented methods and compounds are, as a matter of law, "patented  
 27 inventions" under § 271(e)(1). (ECF No. 213 at 24-27.) Santaris argued, for example,  
 28 that "Momenta[, 686 F.3d 1348 (Fed. Cir. 2012),] leaves no room for Isis to argue that

1     Proveris Scientific Corp. v. Innovasystems, 536 F.3d 1256 (Fed. Cir. 2008), limits the  
 2 Safe Harbor to the use of patented inventions that are themselves the subject of FDA  
 3 approval.” (Id. at 25.)

4         In denying Santaris’s second motion for summary judgment, this Court  
 5 considered Santaris’s reading of Momenta and Proveris and concluded that Proveris  
 6 could indeed be read to limit the meaning of “patented invention” as used in §  
 7 271(e)(1). (ECF No. 250 at 18 n.6.)

8         Judge Moskowitz reached the same conclusion, albeit from a slightly different  
 9 perspective, in denying Santaris’s first motion for summary judgment:

10         The Safe Harbor does not apply . . . when a biological compound is used  
 11 to perform “basic scientific research” or as a “research tool.” “Basic  
 12 scientific research” is performed when the researcher “lacks the intent to  
 13 develop a particular drug or a reasonable belief that the compound will  
 14 cause the sort of physiological effect the researcher intends to induce.”

15         [ECF No. 53 at 6 (citing Merck, 545 U.S. at 205-06).] Judge Moskowitz went on to  
 16 explain “research tools” as

17         patented inventions that are “used in the development of . . . regulatory  
 18 submissions, but, [are] not [themselves] subject to the [regulatory]  
 19 approval process.” Proveris Scientific Corp. v. Innovasystems, Inc., 536  
 20 F.3d 1256, 1265 (Fed. Cir. 2008). For example, in PSN Illinois, LLC v.  
 Abbott Laboratories, No. 09 C 5879, 2011 WL 4442825, at \*4-6 (N.D. Ill.  
 Sept 20, 2011), the [c]ourt found that the defendants’ use of a patented  
 protein receptor was a “research tool,” where the receptor was used only  
 to perform tests on other drug candidates that did not themselves  
incorporate the patented invention. “They were using a patented  
 invention to develop their own patentable product. . . . 271(e)(1) offers no  
 protection for such activity.” Id. at \*6.

21 (ECF No. 53 at 6-7.)

22         While Judge Moskowitz did not directly address the meaning of “patented  
 23 invention” under § 271(e)(1), Judge Moskowitz observed that “research tools” do not  
 24 qualify for protection under § 271(e)(1). And, based on case law interpreting the term  
 25 “patented invention” as used in § 271(e)(1), both this Court and Judge Moskowitz  
 26 found summary judgment inappropriate as to whether Isis’s patented methods and  
 27 compounds are, as a matter of law, “patented inventions” under § 271(e)(1). Thus, in  
 28 addition to concluding that Defendant’s third claim of error is untimely under Civil

1 Local Rule 7.1.i.2, the Court finds Defendants have merely reiterated an argument that  
 2 two courts have considered and rejected. The Court will therefore deny Defendants'  
 3 motion for reconsideration as to the third claim of error.

4 As such, only Santaris's first claim of error remains. While the Court has found  
 5 the declaration Defendants submitted in support of their motion for reconsideration  
 6 does not comply with Civil Local Rule 7.1.i.1, the Court will nonetheless review  
 7 Defendants' first claim of error, as it is based on arguments that the Court has not  
 8 previously considered and that Defendants could not have been expected to raise  
 9 previously.

10 Defendants argue the Court erred when it read Classen Immunotherapies, Inc.  
 11 v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2012), and Momenta Pharmaceuticals, Inc.  
 12 v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012), as standing for the  
 13 proposition that, "regardless of the stage of the regulatory process in which a patented  
 14 invention is used to obtain information, the information derived from using the  
 15 patented invention must be 'reasonably related' to the type of information required by  
 16 the FDA at some point during the regulatory process." (ECF No. 250 at 16.)

17 Defendants argue the foregoing reading of Classen and Momenta is contrary to  
 18 § 271(e)(1) and case law interpreting that section because the safe harbor covers  
 19 infringing activities that produce the types of information that are "relevant" to FDA  
 20 submissions—not types of information that are "required" by the FDA. Defendants  
 21 further argue that, to the extent Momenta and Classen include the "required" language,  
 22 Momenta and Classen apply only to post-regulatory approval activities. (ECF No. 258-  
 23 1 at 9-10.) In that vein, Defendants argue "pre-submission experiments . . . fall within  
 24 the safe harbor as long as such experiments are potentially 'relevant' to an FDA  
 25 submission." [Id. at 10 (citing Merck, 545 U.S. 207-08).]

26 Ultimately, whether the Court agrees with Defendants will not change the  
 27 outcome of this Court's ruling on Defendants' second motion for summary judgment.  
 28 Regardless of the type of information that Defendants anticipated they would derive

1 from the collaboration agreements, the Court would still conclude that the uncertainties  
 2 inherent in the collaboration agreements at the time of contracting preclude summary  
 3 judgment on the issue of whether Santaris's entering the collaboration agreements fell  
 4 within the safe harbor.

5       Turning to the substance of Defendants' arguments, the Court concludes that its  
 6 reading of Classen and Momenta was not clear error. In Eli Lilly & Co. v. Medtronic,  
 7 Inc., the Supreme Court qualified the type of information submitted to the FDA as  
 8 "information necessary to obtain regulatory approval." 496 U.S. 661, 664 (1990)  
 9 (emphasis added); see also Classen, 659 F.3d at 1071 (quoting "necessary" language  
 10 from Eli Lilly). In Momenta, the Federal Circuit likewise qualified the type of  
 11 information as the "necessary information demanded by the 'Federal law.'" 686 F.3d  
 12 at 1359 (emphasis added). Moreover, Classen makes clear that the type of information  
 13 derived from infringing activities does matter: "The statute does not apply to  
 14 information that may be routinely reported to the FDA, long after marketing approval  
 15 has been obtained." 659 F.3d at 1070.

16       These qualifications on the type of information derived from otherwise  
 17 infringing activities find further support in the plain language of § 271(e)(1), which  
 18 exempts acts of infringement undertaken "solely for uses reasonably related to the  
 19 development and submission of information under a Federal law." (Emphasis added.)  
 20 "'Under a federal law' . . . encompasses all 'materials the FDA demands in the  
 21 regulatory process.' Momenta, 686 F.3d at 1356.

22       Finally, the Court finds no support for Defendants' argument that the type of  
 23 information derived from infringing activities varies depending on whether the  
 24 infringing activities take place pre- or post-regulatory approval. To the contrary, at  
 25 least one other district has concluded, "'Momenta clarified that there is no pre/post FDA  
 26 approval dichotomy under the safe harbor provision.' Classen Immunotherapies, Inc.  
 27 v. Shionogi, Inc., 2014 WL 323947, at \*6 (D. Md. Jan. 29, 2014).

28       Having addressed all three of Defendants' claims of error, the Court concludes

1 Defendants are not entitled to the extraordinary remedy of reconsideration. The Court  
2 next addresses Defendants' alternative request for certification of the February 27,  
3 2014 order for interlocutory appeal.

4 **2. Interlocutory Appeal**

5 District courts may certify an issue for interlocutory appeal upon satisfaction of  
6 certain criteria. 28 U.S.C. § 1292(b). Those criteria are: (1) the order involves a  
7 controlling question of law; (2) there is substantial ground for difference of opinion;  
8 and (3) an immediate appeal from the order may materially advance the ultimate  
9 termination of the litigation. In re Cement Antitrust Litigation, 673 F.2d 1020, 1026  
10 (9th Cir. 1982). The court should apply § 1292(b)'s requirements strictly, and should  
11 grant a motion for certification only when exceptional circumstances warrant it.  
12 Coopers & Lybrand v. Livesay, 437 U.S. 463, 475 (1978). The party seeking  
13 certification to appeal an interlocutory order has the burden of establishing the  
14 existence of such exceptional circumstances. Id. "Even then, a court has substantial  
15 discretion in deciding whether to grant a party's motion for certification." Zulewski  
16 v. Hershey Co., 2013 WL 1334159, at \*1 (N.D. Cal. Mar. 29, 2013).

17 Having considered the foregoing criteria, the Court finds that no exceptional  
18 circumstances warrant interlocutory review. Determining whether the safe harbor  
19 applies is a fact-dependent inquiry. Integra Lifesciences I, Ltd. v. Merck KGaA, 496  
20 F.3d 1334, 1347 (Fed. Cir. 2007). Thus, even if the Federal Circuit ultimately reviews  
21 this Court's February 27, 2014 order, the Federal Circuit will be more able to do so  
22 with a complete factual record. See McFarlin v. Conseco Servs., LLC, 381 F.3d 1251,  
23 1259 (11th Cir. 2004) ("§ 1292(b) appeals were intended, and should be reserved, for  
24 situations in which the court of appeals can rule on a pure, controlling question of law  
25 without having to delve beyond the surface of the record in order to determine the  
26 facts."). As such, the Court will deny Defendants' alternative request to certify the  
27 February 27, 2014 order for interlocutory appeal.

28 For the foregoing reasons, Defendants' motion for reconsideration, (ECF No.

1 258), is **DENIED**. The hearing on said motion, currently set for May 30, 2014, is  
2 **VACATED**.

3 DATED: May 28, 2014

4   
5 HON. GONZALO P. CURIEL  
6 United States District Judge

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